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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/063,778 04/22/98 ARIYASU

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001444 HM22/0315  
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EXAMINER

KAUFMAN, C

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

03/15/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/063,778

Applicant(s)

ARIYASU ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-23 is/are pending in the application.
- 4a) Of the above claim(s) 7-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 23 is/are rejected.
- 7) ☒ Claim(s) 2-4 is/are objected to.
- 8) ☒ Claims 1-4 and 7-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed 1/4/00 has been entered.

#### ***Response to Arguments***

Rejections of claims 5 and 6 are moot in view of the cancellation of the claims.

The rejection of claims 1-4 under 35 USC 101 is withdrawn in view of the amendment to claim 1.

The rejection of claims under 35 USC 112, second paragraph is withdrawn in view of the amendment to the claims.

The rejection of claims 1-4 under 35 USC 103 as being unpatentable over Tate et al. in view of Korsmeyer and Ingham is withdrawn in view of the satisfaction of requirements of benefit of priority to Japan application 121578 in the form of a certified copy and translation.

The rejection of claims 1-4 under 35 USC 103 as being unpatentable over Drummond et al. and Ingham is withdrawn in view the amendment to the claim and cannot be applied to new claim 28 due to the structural limitations currently recited in the claim.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

Claims 2-4 are objected to because of the following informalities: as amended the claims now say "which consists the amino", but --of-- should be added before "amino". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112, First Paragraph***

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites a nucleotide sequence at least 90% identical to SEQ ID NO:7 and which encodes a contiguous amino acid sequence which conserves amino acid residues corresponding

to Glu-155 and one or more of Ala-14, Gly-29, and Ala-46 of the amino acid sequence aligned with SEQ ID NO:7. Applicants point to basis for this claim in the paragraph bridging pages 23-24 of the specification which describes the mouse Dhh sequence of SEQ ID NO:7 and in the exhibit showing amino acid sequence alignment of SEQ ID NO:7 with other proteins. While it disclosed that human Desert hedgehog protein may differ from other Dhh sequences of other species, this is a general concept. There is no disclosure of a protein which differs specifically as described in claim 23. The specification does not disclose specific amino acids which are conserved in human Dhh sequences. Further, while the specification says that mouse Dhh is about 89% identical to SEQ ID NO:7 (a partial coding nucleotide sequence for human Dhh which is the same as nucleotides 49-596 of SEQ ID NO:6), there is no disclosure of a human Dhh which is "at least 90% identical" to SEQ ID NO:7 as recited in claim 23. It does not appear that Applicants had conceived a such a human Dhh protein with the particular requirements of conservation of amino acids and minimum % identity as stated in claim 23, and were only in possession of the human Dhh protein consisting of the amino acid sequence of SEQ ID NO:1.

### ***Claim Rejections - 35 USC § 112***

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite because SEQ ID NO:7 is a nucleotide sequence (see section (ii) MOLECULAR TYPE) and so one cannot align an amino acid sequence with it.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1646

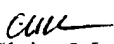
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

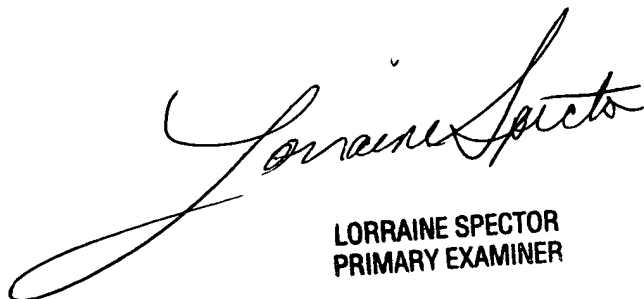
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

  
Claire M. Kaufman, Ph.D.  
Patent Examiner, Art Unit 1646  
March 9, 2000

  
LORRAINE SPECTOR  
PRIMARY EXAMINER